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April 16, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
White Oak, RM 322346
Silver Spring, MD 20993

Dear Commissioner Gottlieb,

I write to express my concern about the Food and Drug Administration's lack of urgency in addressing the threat of arsenic in our food supply, particularly as it relates to young children. A recent report by the U.S. Governmental Accountability Office (GAO), *Federal Efforts to Manage the Risk of Arsenic in Rice*, highlights many of those concerns and I seek to clarify FDA's commitment to GAO's recommendations for the agency's role in managing the risk of arsenic in rice.

Arsenic is a natural element that is most toxic in its inorganic form. In addition to being a known carcinogen, chronic exposure to arsenic has been linked to cardiovascular disease, skin lesions, respiratory disorders, and diabetes.[1] Accordingly, the Environmental Protection Agency limits concentrations of arsenic in all forms in drinking water to 10 parts per billion. The Food and Drug Administration has established a limit of 10 parts per billion in bottled water, and has also proposed a limit of 10 parts per billion in apple juice. However, there are no Federal limits for arsenic in most foods, including rice for adults and children or baby foods.

Rice is a staple food for many individuals across the United States and is often one of the first foods fed to infants. Your agency has found that inorganic arsenic has been detected in an infant's first foods, such as infant rice cereal and brown rice syrup used in an increasing number of products including toddler formula and snack bars.[2] Inorganic arsenic has also been found in other rice products including children's breakfast cereals and rice itself. A study released in December

[1] Nachman, K.E., et al., *Mitigating dietary arsenic exposure: Current status in the United States and recommendations for an improved path forward.* Science of the Total Environment. (March 1, 2017). https://www.sciencedirect.com/science/ article/pii/S0048969716328005?via%3Dihub#bi0005.

[2] *Questions & Answers: Arsenic in Rice and Rice Products*. U S Food and Drug Administration, Center for Food Safety and Applied Nutrition. (November 25, 2017). www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm319948.htm.

2017 by Healthy Babies Bright Futures found there is six times more arsenic in infant rice cereal than in other types of infant cereal.[3] Rice is the most common food for many young children with unique health needs, including children with Celiac disease and children with swallowing difficulties and gastrointestinal reflux. Exposure to elevated arsenic levels is especially concerning for young children because of the potential long-term cognitive and behavioral problems.[4] Accordingly, I concur with the suggestion from university researchers and consumer protection groups outlined in the GAO report, that the FDA should also establish limits for other rice-based products that are consumed by children.[5]

In March of 2016, FDA issued a draft risk assessment of the human health effects from long-term ingestion of arsenic in rice. This also included draft guidance to set an action level of 100 parts per billion for inorganic arsenic in infant rice cereal. Research teams and public health experts noted there were gaps in the 2016 risk assessment, including the failure to adequately consider neurodevelopmental harm, to establish a limit that protects children from arsenic in all rice-based foods, and to adequately consider risks for highly exposed groups (e.g., Hispanic and Asian families, or children with celiac disease). It has been two years and FDA has not addressed these gaps nor finalized the draft guidance. GAO highlighted this inaction noting that "FDA has not fully taken action on… communicating and reporting on risks" associated with arsenic in rice.[6] I am also concerned that FDA is unable to commit to a specific timeline for updating the risk assessment on arsenic in rice as per GAO's recommendation to incorporate new scientific information and clarify next steps for consumers and industry partners. [7]

In order to address these concerns please provide detailed responses to the following questions relating to FDA's role for reducing exposure of arsenic in rice:

1. The FDA did not fully concur with the GAO's recommendation to develop a timeline for updating the risk assessment of arsenic in rice. How does FDA plan to address the gaps that have been identified in its 2016 risk assessment that may leave an unacceptably high risk for children?

2. In their response to the second GAO recommendation the FDA "committed to finalizing the draft guidance establishing an action level of 100 ppb for inorganic arsenic in infant

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[3] Houlihan, Jane. *Arsenic in 9 Brands of Infant Cereal.* Healthy Babies Bright Futures. (December 2017). http://www.healthybabycereals.org/sites/healthybabycereals.org/files/2017-12/HBBF_ArsenicInInfantCerealReport.pdf.

[4] Morris, Steve D., *Federal Efforts to Manage the Risk of Arsenic in Rice.* United States Government Accountability Office. (April 16, 2018), 15.

[5] Ibid., 21.

[6] Ibid., 16.

[7] Ibid., 45.

rice cereal … by the end of 2018."[8] Is the FDA still committed to finalizing the draft guidance within this time line? If so, what actions has FDA taken to finalize the draft guidance?

3. Would the FDA consider expanding the action level of 100 ppb for inorganic arsenic in infant rice cereal to include, for example, the European Union's definition of "rice destined for the production of food for infants and young children"[9]?

4. If the draft guidance for arsenic in infant rice cereal is finalized, how will FDA communicate the new guidance to health care providers and consumers, and how will it be enforced?

5. In response to the fourth GAO recommendation, FDA agreed that "a mechanism for better coordinating with USDA on development of methods to detect contaminants in food would be worthwhile."[10] Is FDA still committed to improving coordination with USDA to detect food contaminants? If so, what steps have FDA taken to develop a plan to address existing issues with inter-agency coordination as it relates to detecting food contamination?

6. What is FDA doing to evaluate the risk of arsenic in other rice-based products consumed by infants and children?

I urge you to fulfill your responsibility as the national regulatory authority on food safety and protect some of America's most vulnerable by finalizing the draft guidance on arsenic in infant rice cereal and setting a timeline for updating the risk assessment on arsenic in rice. I look forward to hearing your response to this pressing matter.

Sincerely,

Rosa L. DeLauro
Member of Congress

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[8] Ibid.

[9] *Amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs.* Official Journal of the European Union. (June 25, 2015) https://eur-lex.europa.eu/legal content/GA/ALL/?uri=CELEX%3A32015R1006.

[10] Morris, Steve D., *Federal Efforts to Manage the Risk of Arsenic in Rice.* United States Government Accountability Office. (April 16, 2018), 46.